
SAYENKO KHARENKO

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If you could provide our readers with your philosophy when you founded Sayenko Kharenko in 2004. What were the market needs that were perhaps missing that you identified and wanted to address?

If you look at the top 5 law firms in Ukraine, Sayenko Kharenko definitely is not the oldest one. However, before setting up an office in 2004 both I and other founding partners have been active on the market for well over 10 years. At that time Ukrainian law firms concentrated on the traditional practices, such as litigation and basic corporate work, while Western law firms knew how to present their legal advice properly, but did not always understand local realities and legislative framework. When the demand was shifting towards sophisticated transactional spheres – such as capital markets, international finance, M&A, competition law, international trade, we found ourselves among the very few lawyers capable to handle complex cross-border work and could make good use of our competitive strengths: local expertise, diverse international education, experience in cross-border matters and western style approach to doing business. We serviced much of the investment boom that started in 2005, and topped transactional leagues tables in Ukraine during the first year on the market. This helped us build a strong recognizable brand and soon transform into a top transactional and dispute resolution law firm we are now.

How important is the pharmaceutical industry for Sayenko Kharenko?

The pharmaceutical industry gradually became a special-focus sector for Sayenko Kharenko. Initially, we handled a number of M&As between the big players which had some implication for the local market and required merger clearance in Ukraine. This gave us a deep understanding of how the industry works and what the important issues are. We have now shifted from occasionally dealing with pharmaceutical sector in transactional matters to advising industry players on a regular basis on a broad range of legal issues.

For the lawyers in our trade practice, the situation is a little different. They became involved with the pharmaceutical industry when first foreign companies tried to pioneer into the market through distribution contracts. For Ukraine, it was a new kind of legal relationship. Around 2004-2005, members of our team became the local experts for IDI (International Distribution Institute) set by ICC Trade Committee that is very active in their policy of distribution, franchising and agency agreements. This institution provides a platform for debating many industry issues, including also legal aspects of IP rights and registration. Unfortunately, infringements of IP rights were very common in Ukraine at that time, but foreign companies were still rushing to enter the market in order to benefit from the opportunities. They arrived through representative offices and distributors, gradually expanding through local subsidiaries and some are even moving towards local manufacturing and clinical research. We try to follow the developments of the business of our clients, combining the efforts of our trade, competition and dispute resolution practices together.

Would you say there is a trend for MNCs to move to an LLC structure rather than simply representative office?

Yes, as the market develops and multinational companies expand their operations, they try to segregate risks arising from commercial operations by setting up subsidiary companies, primarily in the form of limited liability companies (LLCs). However, a representative office may be a more appropriate solution for minimal market presence limited to market research and other auxiliary functions.

Let's talk about the competition issues and why they are important.

Pharmaceutical industry and the principles of competition law and policy are very closely connected even, perhaps, more so than other industry sectors. This is illustrated by two significant realizations: (1) medical drugs are supposed to cure people, which is the principal reason why the Ukrainian government and, in particular, the Antimonopoly Committee of Ukraine (the "AMC") subject pharmaceutical companies, especially foreign entities, to additional scrutiny and (2) any company, even a very small one, can have a monopoly (dominant) position as markets run the risk of being very narrowly defined by the regulator.

The social importance of the pharmaceutical industry has motivated the AMC to conduct full-blown investigations on a regular basis. As a consequence, companies should be particularly vigilant when devising their marketing and pricing policies. With respect to the former, special care needs to be taken to ensure that advertisements disseminated in the mass media do not amount to false advertising – such as making false claims about a drug's abilities to cure cancer or some other illness in a situation where it can only relieve the symptoms. This is an area in which the AMC has recently been particularly aggressive, setting fines of more than EUR 100,000. As an illustration of increased scrutiny by the regulator, all TV stations were requested to provide the AMC with video material of all adverts aired on their channels last year. To reduce the risk of prosecution, pharmaceutical companies can now obtain comfort letters from the regulator, confirming that their prospective advertisements do not raise any unfair competition concerns.

"It was a great privilege for us to be the only law firm in Ukraine last year to have obtained such a comfort letter from the AMC on behalf of one of our clients, who just happens to be quite active in the pharmaceutical sector."

Equally, the AMC investigates the industry to ensure that companies' pricing policies are backed by strong objective and economic justifications. This is because any evidence of a synchronized change in pricing (even a seasonal one) creates a rebuttable presumption of a cartel, punishable by a fine of up to 10% of gross worldwide turnover. For example, the regulator is particularly concerned with prices of medicines going up in winter months when there are more cases of flu-like epidemics. Problems occur particularly when companies cannot identify what sort of evidence needs to be submitted to justify such seasonal price changes.

Since many companies may enjoy a monopoly (dominant) market position, there is an additional risk that their market behavior can be viewed as abusive of their dominant position, resulting in a fine of up to 10% of gross worldwide turnover. Thus, during investigations conducted by the AMC, large multinationals, particularly those in the pharmaceutical industry, regularly turn to us in order to ensure that their current and prospective market policies do not amount to any abusive and anticompetitive conduct.

Also, when it comes to mergers and acquisitions in the pharmaceutical industry, which usually involves companies with high market shares, undertakings are subject to even more scrutiny as there is an increased risk of Phase II investigations that can prolong the merger review process by up to three months (and even more on some occasions). As companies usually face tight deadlines, we often need to ensure that merger approvals are obtained on an expedited basis. Namely, during the merger filing process (of which we do approximately 40 per year), our team consisting of 10 competition lawyers (with 2 being ex-AMC officers) rely on their close cooperation with the AMC officials to secure an efficient and effective outcome.

We have been hearing from international pharmaceutical companies that the authorities are realizing that the current healthcare structure is not sustainable and they are implementing measures that maybe in 4 years time will be introduced a reimbursement system, private insurance firms and these are the opportunities that we want to transmit to our readers. Speaking about opportunities and being an M&A expert, how do you see the M&A climate?

From an M&A perspective, the Ukrainian market may look quite attractive based on statistical growth figures, but everybody has to realize why the estimated profits are so high: because the legal risks are also very high. Any due diligence review would reveal a skeletons in the closet of the targets' affairs. This is especially true of the privatized companies or companies that undergone numerous reorganizations which hardly ever go without violations. These problems tend to be raised by minority shareholders or other interested parties after a large multinational has completed the acquisition of the target. Also, some tax optimization schemes might prove to be unacceptable although these schemes contributed to high profits shown to the purchaser before acquisition. Once these schemes are dropped, the business might be not as profitable as when it was run by local entrepreneurs.

Finally, many deals might grind to a halt because of the apparent mismatch of the sellers and buyers' expectations. Yet where a decision to sell is driven by a growing pressure from the creditors or other conditions unfavorable to the seller, the deal is much more likely to reach its closing stage.

Do you feel that the national industry will eventually clean up so that M&A can become a possibility?

Last year we have seen quite a few of the completed and struck deals, so some activity on the M&A market is already clearly visible. There is definitely a trend for the local industry to "clean up" in order to be more attractive. Moreover, we have seen the legal framework being gradually improved to attract foreign investors. Yet the major country risks remain the same: inconsistent application of the laws by various regulators, corrupt judiciary and weak enforcement. However, as I mentioned, these risks pay off with the much higher yields on investment than elsewhere in the developed economies. We have also seen the government making an effort to provide incentives for foreign companies to localize production. This regulatory change is likely to contribute to the M&A activity in the pharmaceutical sector.

You mentioned you were having more and more Ukrainian clients. How do you deal with the uncertainties and ambiguities of their operations?

Our local clients usually do not ask our opinion on the existing uncertainties in their modus operandi, but instead require our assistance in cleaning up their business to minimize operational risks. Therefore, professionally, we have no issue on this because we do not need to find compromises with our professional ethics.

What is your vision of the Ukrainian pharmaceutical market in the upcoming 5 years?

Ukraine is one of the biggest consumer markets in Europe and remains quite attractive for investments into the pharmaceutical sector. Experts agree that the Ukrainian market will most probably remain "the generics market" for quite some time, thus investments into the development of local capacities for the production of essential generic drugs will probably be the market trend for the upcoming years.

We also have reasons to believe that industry players will be taking further steps to motivate consumer spending and consumption. In 2011 the consumer spending on medicines in Ukraine was estimated at USD 2.1 billion, which translates into USD 65 per capita and is almost twice as lower as, let's say, in Russia. The market for innovative products will mostly be driven by strong import growth.

Overall the pharmaceutical market will grow more rapidly if the government manages to implement an effective health insurance system and remove burdensome and excessive regulatory barriers. I feel that

currently one of the problems facing the industry is insufficient communication with law makers and regulators. The maize of regulations applied to the procedure of the registration of generic products is an evident example. Based on the success-stories of other industries in Ukraine, I can conclude that some of the pharmaceutical sector problems can easily be solved by discussion between the business and the government.

What would you like to say to the international business readers of Pharmaceutical Executive?

We encourage pharmaceutical companies to have a closer look at business opportunities that the Ukrainian market has to offer.

Industry players whose business development strategies expand to Eastern European markets can always rely on our local expertise and experience on all legal issues associated with doing business in Ukraine.